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By:   
Aaron Hokamura

PATENT  
Attorney Docket No.: 082368-003300US  
Client Reference No.: E1-A0306Y1P-US

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of:

YASUDA and YAMAZAKI

Application No.: 10/528,353

Int'l Application No.: PCT/JP03/12075

Int'l Filing Date: September 22, 2003

For: COMBINATION DRUG

Examiner:

Art Unit:

INFORMATION DISCLOSURE  
STATEMENT UNDER 37 CFR §1.97 and  
§1.98

Commissioner for Patents  
P.O. Box 1450  
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Sir:

The references cited on attached form PTO/SB/08A and PTO/SB/08B are being called to the attention of the Examiner. Copies of references AC-AJ, AL and AM are enclosed. In compliance with the requirements of 37 CFR §1.98(a)(2), U.S. Patent Publication documents (References AA and AB) are not enclosed.

References AK and AN are not enclosed. These references were, however, cited in the International Search Report in a corresponding application, along with references AC-AG and AL. Since references AK and AN were cited in the International Search Report, a copy should have been provided directly by the WIPO under the exchange program between the

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U.S.P.T.O., the E.P.O. and the J.P.O. A copy of the International Search Report is attached hereto.

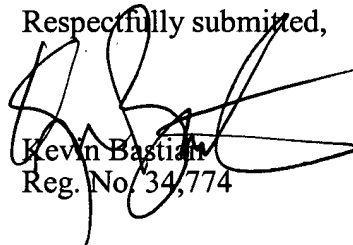
Reference AF is not in English. However, Reference AF was cited on the above-mentioned International Search Report as a category X, Y and A document.

It is respectfully requested that the cited references be expressly considered during the prosecution of this application, and the references be made of record therein and appear among the "references cited" on any patent to issue therefrom.

As provided for by 37 CFR §1.97(g) and (h), no inference should be made that the information and references cited are prior art merely because they are in this statement and no representation is being made that a search has been conducted or that this statement encompasses all the possible relevant information.

Applicant believes that no fee is required for submission of this statement. However, if a fee is required, the Commissioner is authorized to deduct such fee from the undersigned's Deposit Account No. 20-1430. Please deduct any additional fees from, or credit any overpayment to, the above-noted Deposit Account.

Respectfully submitted,





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Substitute for form 1449B/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)			<b>Complete if Known</b>		
			Application Number	10/528,353	
			Filing Date	September 22, 2003	
			First Named Inventor	Nobuyuki Yasuda	
			Art Unit		
			Examiner Name		
Sheet	2	of	2	Attorney Docket Number	082368-003300US

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS				
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.		T <sup>2</sup>
	AK	HINKE, S.A. <i>et al.</i> ; "Metformin effects on dipeptidylpeptidase IV degradation of glucagon-like peptide-1"; <u>Biochem. Biophys. Res. Commun.</u> ; March 15, 2002; pp. 1302-1308; vol. 291, No. 5		
	AL	HINKE, Simon A. <i>et al.</i> ; "On combination therapy of diabetes with metformin and dipeptidyl peptidase IV inhibitors"; <u>Diabetes Care</u> ; August 2002; pp. 1490-1491; Vol. 25, No. 8		
	AM	YAMAZAKI, Kazuto <i>et al.</i> ; "The combination of metformin and a dipeptidyl peptidase IV inhibitor prevents 5-fluorouracil-induced reduction of small intestine weight"; <u>European Journal of Pharmacology</u> ; 2004; pp. 213-218; Vol. 488		
	AN	YASUDA, N. <i>et al.</i> ; "Enhanced secretion of glucagons-like peptide 1 by biguanide compounds"; <u>Biochem. Biophys. Res. Commun.</u> ; November 15, 2002; pp. 779-784; Vol. 298, No. 5.		

Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

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Sheet **1** of **2****Complete if Known**

Application Number	10/528,353
Filing Date	September 22, 2003
First Named Inventor	Nobuyuki Yasuda
Art Unit	
Examiner Name	
Attorney Docket Number	082368-003300US

**U.S. PATENT DOCUMENTS**

Examiner	Cite No. <sup>1</sup>	Document Number Number Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	AA	2004/0082570 A1	04-29-2004	Yoshikawa et al.	
	AB	2004/0116328 A1	06-17-2004	Yoshikawa et al.	

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>5</sup>
		Country Code <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
	AC	WO	01/52825	A2,A3	07-26-2001	Novartis AG		<input type="checkbox"/>
	AD	WO	01/97808	A1	12-27-2001	SmithKline Beecham PLC and SmithKline Beecham Corporation		<input type="checkbox"/>
	AE	WO	02/02560	A2/A3	01-10-2002	Novo Nordisk A/S		<input type="checkbox"/>
	AF	WO	02/068420	A1	09-06-2002	Boehringer Ingelheim Pharma KG		<input type="checkbox"/>
	AG	WO	03/004496	A1	01-16-2003	Novo Nordisk A/S		<input type="checkbox"/>
	AH	WO	03/104229	A1	12-18-2003	Eisai Co., Ltd.		<input checked="" type="checkbox"/>
	AI	WO	2004/050656	A1	06-17-2004	Eisai Co., Ltd.		<input checked="" type="checkbox"/>
	AJ	EP	1 338 595	A2,A3	08-27-2003	Eisai Co., Ltd.		<input type="checkbox"/>

Examiner  
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Considered

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<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Kind Codes of U.S. Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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